

6-21-04

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## Patent Application Attorney Docket No.PC25240A

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: Mail Stop Amendments, Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on this 1805 day of June, 2004.

By Selly Martin (Signature of person mailin Kelly A. Smith

(Typed or printed name of person)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Timothy A. Hagen, et al.

APPLICATION NO.: 10/763,340 : Examiner:

FILING DATE: January 23, 2004 : Group Art Unit: 1615

TITLE: AZITHROMYCIN DOSAGE FORMS WITH :

REDUCED SIDE EFFECTS

Hon. Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

Sir:

## INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. § 1.97 ET SEQ.

Applicant(s) herein make(s) available to the U.S. Patent and Trademark Office a copy of PTO-FB-A820 which lists the references cited by the applicant(s), copies of which are enclosed.

The Examiner is requested to consider carefully the complete text of these references in connection with the examination of the above-identified application in accord with 37 C.F.R. § 1.104(a). It is believed the Examiner will concur with applicant's belief that the subject matter presently claimed is neither anticipated nor rendered obvious by the foregoing references.

It is requested that the references listed on the attached form PTO-FB-A820 be included in the "References Cited" portion of any patent issuing from this application (M.P.E.P. § 1302.12).

A prompt and favorable response is earnestly solicited.

Date: 18 June 2004

Respectfully submitted,

Scott Alexander McNeil Attorney for Applicant(s)

Reg. No. 37,185

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(860) 686-1848

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						U.S	. PATEN	IT DOC	UMENTS						
EXAMINER INITIAL		DOCUMENT NUMBE				MBER	1		DATE	NAME		CLASS	SUBCLASS	FILING IF APPRO	DATE
	US	5	1	6	9	6	4	5	12/8/92	Shukla, et al.		424	499		
	us	5	6	3	9	0	4	6	5/27/97	Catania, et a	al.	424	441		
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	us	5	7	0	5	1	5	0	1/6/98	Broad, et a	J.	424	499		
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_	us	6	0	5	8	8	5	9	5/30/00	Curatolo, et	al.	424	490		
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	us	6	5	0	0	4	5	5	12/31/02	Chhabra, et	al.	424	474		
	υs	6	9	6	9	4	6	3_	5/27/03	Patel, et al		424	497		
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	US	6	6	9	2	7	5	7	2/17/04	Burnside, et	al.	424	489		
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DOCUMENT NUMBER									DATE	COUNTRY		CLASS	SUBCLASS	TRANS	LATIC
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everal sheets if necessary)	APPLICANT Timothy A. Hagen, et al.								
	FILING DATE	January 23, 2004	GROUP	1615					
OTHER DOCL	JMENTS (Includ	ding Author, Title, Date, Pen	tinent Pages, Et	c.)					
Foulds, G., et al., "The effects of an antacid or cimetidine on the serum concentrations of azithromycin", J. Clin. Pharmacol. 1991 Feb; 31(2): 164-7 (Abstract)									
Amsden, G.W., et al., "Serum and WBC pharmacokinetics of 1500 mg of azithromycin when given either as a single dose or over a day period in healthy volunteers", J. Antimicrobial Chemotherapy (2001), 47(1), 61-66 (Abstract)									
Zithromax® azithromycin tablet 250 mg, Quantitative Composition of the Tablet Blend									
Zithromax® azithromycin for oral suspension composition 200 mg/5mL, 200mg/5mL Drug Product									
Zithromax® azithromycin for oral suspension composition 1 gram sachet, Quantitative Composition of the Drug Product									
Zithromax® azithromycin for oral suspension composition 100 mg/5mL, Quantitative Compositions of the Drug Products									
Zithromax® (azithromycin tablets and azithromycin for oral suspension), Full U.S. Prescribing Information, 70-5179-00-4									
Zithromax® (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Prescribing Information, 69-4763-00-9									
Food and Drug Administration Center for Drug Evaluation and Research Approved Drug Products with Therapeutic Evaluations, 24 Edition, Orange Book Listings of Azithromycin Dosage Forms									
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	Poveral sheets if necessary)  OTHER DOCL  Foulds, G., et al., "The effects of an a Feb; 31(2): 164-7 (Abstract)  Amsden, G.W., et al., "Serum and Widay period in healthy volunteers", J. A Zithromax® azithromycin tablet 250 m Zithromax® azithromycin for oral susp Zithromax® azithromycin for oral susp Zithromax® azithromycin for oral susp Zithromax® (azithromycin tablets and Zithromax® (azithromycin capsules) (69-4763-00-9  Food and Drug Administration Center	APPLICANT FILING DATE  OTHER DOCUMENTS (Included Foundary)  Foundary G., et al., "The effects of an antacid or cimetidined Feb; 31(2): 164-7 (Abstract)  Amsden, G.W., et al., "Serum and WBC pharmacokinetic day period in healthy volunteers", J. Antimicrobial Chemical Chemic	APPLICANT Timothy A. Hagen, et al.  FILING DATE January 23, 2004  OTHER DOCUMENTS (Including Author, Title, Date, Period Service)  Foulds, G., et al., "The effects of an antacid or cimetidine on the serum concentrations of azifeb; 31(2): 164-7 (Abstract)  Arnsden, G.W., et al., "Serum and WBC pharmacokinetics of 1500 mg of azithromycin where day period in healthy volunteers", J. Antimicrobial Chemotherapy (2001), 47(1), 61-66 (Abstract)  Zithromax® azithromycin tablet 250 mg, Quantitative Composition of the Tablet Blend  Zithromax® azithromycin for oral suspension composition 200 mg/5mL, 200mg/5mL Drug P  Zithromax® azithromycin for oral suspension composition 1 gram sachet, Quantitative Composition 200 mg/5mL, Quantitative Composition 200 m	APPLICANT Timothy A. Hagen, et al.  FILING DATE January 23, 2004 GROUP  OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.  Foulds, G., et al., "The effects of an antacid or cimetidine on the serum concentrations of azithromycin", J. Clin. Feb; 31(2): 164-7 (Abstract)  Amsden, G.W., et al., "Serum and WBC pharmacokinetics of 1500 mg of azithromycin when given either as a siday period in healthy volunteers", J. Antimicrobial Chemotherapy (2001), 47(1), 61-66 (Abstract)  Zithromax® azithromycin tablet 250 mg, Quantitative Composition of the Tablet Blend  Zithromax® azithromycin for oral suspension composition 200 mg/5mL, 200mg/5mL Drug Product  Zithromax® azithromycin for oral suspension composition 1 gram sachet, Quantitative Compositions of the Drug I Zithromax® azithromycin for oral suspension composition 100 mg/5mL, Quantitative Compositions of the Drug I Zithromax® (azithromycin tablets and azithromycin for oral suspension), Full U.S. Prescribing Information, 70-51 Zithromax® (azithromycin capsules) (azithromycin tablets) and (azithromycin for oral suspension), Full U.S. Prescribing Products with Therape Edition, Orange Book Listings of Azithromycin Dosage Forms					

Conforms with FORM PTO-FB-A820 INFORMATION DISCLOSURE